


|  |   |                              |
|--|---|------------------------------|
|  <b>BROWN</b> | <b>Institutional Animal Care<br/>and Use Committee<br/>(IACUC):</b> | SOP 10.10.08                 |
|  | <b>SOP for IACUC<br/>Semiannual Inspections</b>                     | Effective Date: June 4, 2020 |

## 1.0 Standard Operating Procedure (SOP) Purpose

The purpose of this SOP is to define the process by which the IACUC conducts semiannual inspections of animal facilities and laboratories at Brown University.

## 2.0 SOP

This SOP is for use by the members of the IACUC, Animal Research Compliance (ARC), facility managers, and Principal Investigators (PIs) responsible for the management and operation of animal research labs. The Brown IACUC strives to maintain a spirit of collegiality in its approach to semiannual inspections, and aims to leverage its face-to-face interactions with PIs, lab members, and facility managers to provide education and increase awareness of IACUC policies and regulatory requirements.

### 2.1 Background

All animal facilities housing live, vertebrate animals for research, testing, or teaching purposes must be inspected by the IACUC semiannually, and no less frequently than once every six months. An animal facility includes any buildings, rooms, areas, enclosures, vehicles, and [Satellite facilities](#) used for animal confinement, transport, maintenance, breeding, procedures, or experiments. Every IACUC member is expected to participate in semiannual inspections on a regular basis. IACUC members will not be excluded from an inspection in which they wish to participate.

In accordance with Public Health Service Policy (“PHS Policy”), each semiannual inspection will be conducted using The Guide for the Care and Use of Laboratory Animals, 8th edition (“The Guide”) as a basis for evaluation. Any deficiency identified in the inspection report must be categorized as “[Minor](#)” or “[Significant](#),” and an appropriate time frame and a specific date for correction must be included.

### 2.2 Scheduling of Inspections

Routine, semiannual inspections are scheduled in advance. Although not required, the facility manager and/or PI is typically notified of the date and time of the inspections and the rooms to be inspected. It is the responsibility of the facility manager and/or PI to ensure that the room numbers identified are accurate and that the list of rooms is complete. The facility manager and/or PI or a designated alternate serves as a point-of-contact during the inspection of that facility. Random, unannounced inspections may also occur and will be organized by ARC or the IACUC.

Inspection of facilities used only for a short duration will be done, whenever possible, at a time when the animals are housed in those facilities.

### **2.3 Facility Access**

The IACUC must have access to all approved Brown University animal facilities 24 hours per day, seven days a week. Access is defined as the ability to enter an approved animal facility immediately for a pre-scheduled inspection and within two hours of an unannounced inspection. Any exceptions to this access must be mutually agreed upon in writing by the individual responsible for the facility and the inspection team. In some facilities, special entry requirements for non-essential personnel are required because of controlled environments (*e.g.*, specific pathogen-free facilities) or special occupational health issues (*e.g.*, non-human primate facility).

### **2.4 Inspection Team**

Inspection teams are comprised of the individuals necessary to maintain compliance with all applicable regulations. The inspection team will ordinarily include a minimum of two IACUC members for Department of Defense (DOD) funded projects and United States Department of Agriculture (USDA) covered species, one of whom will be a Center for Animal Resources and Education (CARE) veterinarian. PHS policy allows the option of including ad hoc consultants to assist during inspections; Brown's decision to include ad hoc consultants requires approval by the IACUC or the IACUC Chair.

In an effort to minimize administrative burden on PIs and disruption of research, Brown's IACUC will try to coordinate its inspections with other groups within the University that also need to conduct inspections (*e.g.*, Environmental Health and Safety).

### **2.5 Scope of Inspections**

The IACUC evaluates all aspects of the animal facility during the inspection including, but not limited to:

- housing/environmental conditions;
- feed/water/bedding;
- cleaning/sanitation;
- specialized space;
- animal care, including review of medical, procedural and post-operational records;
- personnel training records;
- occupational health and safety;
- infrastructure/construction;
- Brown-owned vehicles used to transport animals; and
- expiration dates, storage and proper labelling of substances administered to animal.

### **2.6 During the Inspection**

During the inspection, the IACUC assesses different aspects of the animal care and use program, as required by the Office of Laboratory Animal Welfare (OLAW) and the USDA. Minor and significant deficiencies and any comments related to the inspected areas are documented. The inspection team will

attempt to highlight all noted deficiencies to the facility manager and/or PI at the time of inspection; however, some deficiencies (*e.g.*, protocol deviations) may not be known at the time of inspection, and will be determined only after the inspection team conducts a post hoc review of its notes and/or relevant IACUC protocols.

The inspectors may request the implementation of immediate corrective actions during the inspection or directly following the inspection, particularly for deficiencies that may have a substantial impact on animal health or human safety.

All findings and observations must be documented in writing in an inspection report. Each inspection report must be submitted to the IACUC for review and approval and a summary of all findings must be included in the comprehensive semiannual report to the Institutional Official (IO).

## **2.7 Following the Inspection**

Following the inspection, the ARC sends a copy of the inspection report to the facility manager and/or PI and assigns correct-by dates and preliminary categorizations (*e.g.*, Minor vs. Significant) for any noted deficiencies. The IACUC ultimately makes the final determination regarding the categorization of any identified deficiencies. It is the responsibility of the facility manager and/or PI to correct the deficiencies by the deadlines cited and to inform ARC when the corrective actions are completed.

The facility manager and/or PI may submit a written request for an extension, with appropriate justification, if the timeline for any corrective action is unattainable. The IACUC Chair or the Chair's designee will determine if the proposed extension will be granted. Denials of requests for extensions are not appealable. ARC documents requests for extensions and the Chair's or designee's determination.

## **2.8 Reporting to the IACUC**

Semiannual inspection reports are provided to the IACUC for review and approval at the convened committee meeting following the relevant inspections. The IACUC may require further actions, request an explanation of any finding, and/or request to modify the correct-by deadlines. Ultimately the IACUC votes to affirmatively approve the semiannual inspection reports and their findings. ARC documents all committee decisions, communicates additional requirements or requests to the responsible individuals, and coordinates appropriate resolution.

## **2.9 Reporting to the IO**

Any Significant Deficiency that is not corrected by the assigned deadline (and for which an extension has not been granted) is reported to the IO and any appropriate regulatory agencies. A Minor Deficiency that is not corrected by the specified correct-by date is reviewed by the IACUC, and follow up action is determined on a case-by-case basis.

The semiannual facility inspections report is provided to the IO every six months and includes a complete list of all facilities where inspections were conducted during the reporting period, dates of inspections, any deficiencies identified, corrective actions and timelines for completion of the corrective actions. Any delays or other issues related to the inspections are documented in this report.

## 2.10 Regulatory Reporting Requirements

The IACUC adheres to the Guidance on Prompt Reporting to OLAW under the PHS Policy and AAALACi reporting requirements when evaluating whether a deficiency identified during the semiannual inspection process requires reporting to an external agency. If the IACUC determines that a report to an external agency is required, the IACUC will provide the facility manager and/or PI with a draft of the report to confirm accuracy before it submits the report to the outside agency.

## 3.0 Definitions

For the purpose of this SOP, the terms below have the following definitions:

**Institutional Official:** The individual who, as a representative of senior administration, bears ultimate responsibility for the animal research program and is responsible for resource planning and ensuring alignment of program goals with the institution's mission. At Brown the Institutional Official is the Vice President for Research.

**Minor Deficiency:** An identified problem for which an immediate solution is not necessary to protect life or prevent distress (*e.g.*, peeling or chipped paint). Ongoing inattention to a Minor Deficiency may result in a chronic problem indicative of a programmatic failure and may constitute a Significant Deficiency.

**Significant Deficiency:** An identified problem that is or may be a threat to the health or safety of animals or personnel. Significant deficiencies can result from an institution's failure to fully understand or implement some aspect of its animal care and use program required by the PHS Policy, or failure to function according to commitments made in its Assurance, and may reach the level of reportable noncompliance.

**Satellite facility:** Any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 12 hours.

## 4.0 Responsibilities

All individuals to whom this SOP applies are responsible for becoming familiar with and following this SOP. University supervisors are responsible for promoting the understanding of this SOP and for taking appropriate steps to help ensure compliance with it.

## 5.0 Related Information

The following information compliments and supplements this document. The information is intended to help explain this SOP and is not an all-inclusive list of policies, procedures, laws and requirements.

**5.1 Related Policies:** N/A

**5.2 Related SOPs:** N/A

**5.3 Related Forms:** N/A

**5.4 Frequently Asked Questions (FAQs):** N/A

**5.5 Other Related Information:** N/A

**6.0 SOP Owner and Contact**

**6.1 SOP Owner:** Vice President for Research

**6.2 SOP Approved by:** Vice President for Research

**6.3 Subject Matter Contact:** Brown University Animal Research Compliance

- Telephone: 401-863-3050
- Email: IACUC@Brown.edu

**7.0 SOP History**

**7.1 SOP Effective Date:** June 4, 2020

**7.2 SOP Last Reviewed:** February 4, 2021

**7.3 SOP Update/Review Summary:** Last reviewed by the IACUC June 2, 2020. This SOP has been converted to align with the University's new SOP template. Guidance superseded by this SOP:

- Guidance for IACUC Semiannual Inspections, Date of IACUC Review and Approval: June 2, 2017